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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/382,615	08/25/1999	EDWARD L. SINOFSKY	101327-126	5467

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EXAMINER

SHAY, DAVID M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/382,615

Applicant(s)

SINOFSKY ET AL.

Examiner

david shay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 13, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2-9, and 11-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2-9, and 11-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 13, 2005 has been entered.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2-9, and 11-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 17, and 21-24 "said lumen of the deflection member" lacks positive antecedent basis. In claim 9, the antecedent of "it's" is unclear, this would be remedied by replacing "it's" with -- the -- and inserting -- thereof -- at the end of the claim.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-9, 11, 12, 15, 16 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell et al in combination with Heaven. Kittrell et al teach a device as claimed except for the particular deflection member. Heaven teaches a deflection member (see figure 1) which has an outer sheath (14), a cut out and, when viewed in profile, an hourglass shape wherein the width of the cut away portion is less than the diameter of the non-cut away portion. It would have been obvious to insert the device of Kittrell et al into the device of Heaven or to employ the elongate and the deflection member of Heaven in the device of Kittrell

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et al in place of, for example, element 140 in figure 14, since Kittrell et al envision a wide variety of deflection mechanisms; to provide multiple deflection members to allow deflection in multiple directions; and to form the deflection member so as to run from the proximal end of the catheter, since this would provide greater strength as shown by Heaven, thereby rendering the cutout at the distal end of the deflection member, and to form the member or surround the member with a fluoropolymer, since these are notorious for use in catheters and provide a lubricious surface, official notice which has already been taken, and to provide the particular location of the cutout, since this is not critical and provides no unexpected result, thus producing a device such as claimed.

Claims 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heaven in combination with Kittrell et al. The teachings of Heaven and Kittrell et al and the motivation for modification and combination thereof are essentially those already set forth above. It would have been obvious to the artisan of ordinary skill to repeatedly advance the fiber device of Kittrell et al when it is inserted through the tubular member of Heaven, since Kittrell et al specify the device is to be advanced through the lumen until the obstruction is removed, thus producing method such as claimed.

Claims 13 and 14 are rejected under 3 U.S.C. 103(a) as being unpatentable over Kittrell et al in combination with Heaven as applied to claim 12 above, and further in view of Vassiliadis et al. Vassiliadis et al teach the use of a gold coating on a laser applicator. It would have been obvious to the artisan of ordinary skill to employ a gold coating, as taught by Vassiliadis, since this would protect tissue from unintended irradiation, thus producing a device such as claimed.

Claims 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell et al in combination with Heaven as applied to claims 17-21 are above, and further in view of Isner et al. Isner et al teach a method of treating tachycardia including inserting a catheter and inserting a fiber therein for applying laser energy to the foci responsible for the tachycardia. It would have been obvious to the artisan of ordinary skill to employ the tachycardia treatment method of Isner et al in the surgical device placement method of Heaven, since Heaven teach that the device can be used with a variety of medical procedures thus producing a method such as claimed.

Applicant has amended the claims to include the limitations of claim 10 in the independent claims, reciting a partially cut-away distal end region. Applicant has argued that the unique form of the deflection member of the instant invention enables complex deformations to be achieved. While this is noted by the examiner, the claims must still read over the art of record. The claims at bar are still very broad, not even reciting any sort of connection between the deflection member and the elongate member. And the examiner must note that the element 6 in Figure 1 of Heaven completely fulfills the requirement for a "partially cut-away distal end region" and the instant "comprising-type" claims do not preclude other structures such as the pull wire.

Applicant's arguments filed May 13, 2005 have been fully considered but they are not persuasive. The arguments are not convincing for the reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Thursday from 6:30 a.m. to 5:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak, can be reached on Monday, Tuesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330